

REMARKS

This is in response to the Final Office Action dated April 15, 2009. Applicants are filing herewith a Request for Continued Examination and respectfully request entry of the above amendments and reconsideration of the rejections for the following reasons.

After entry of this amendment, claims 1, 3-8, 10-13, 15-18, and 20-27 are pending of which claims 10, 11, and 22 are withdrawn. Claims 2, 9, 14, and 19 are cancelled without prejudice or disclaimer. The claims have been amended without prejudice or disclaimer and find support *inter alia* in the original claims. The amendments to claims 1 and 8 find further support in original claims 1, 2, 8, and 9, and in the specification, for example, at page 18 line 28 through page 19 line 5. The amendments to claim 5 find further support in the specification, for example, at page 9, lines 20-29. The amendments to claim 13 and new claim 25 find support in original claim 5, and in the specification, for example, at page 13, lines 25-30, and at page 18, lines 28-37. New claim 26 finds support in the specification, for example, at page 18, lines 4-7, 14-22, 26-27, and at page 25, lines 6-11, and Example 4.2. No new matter has been added.

Applicants submit herewith a Sequence Listing which conforms to 37 CFR §§ 1.821-1.825 *via* EFS-Web, and a Statement to Support Filing and Submission in Accordance with 37 CFR §§ 1.821-1.825. The sequence motifs recited in the specification at pages 6 and 7 of the published International Application and which did not appear in the initial Sequence Listing have been added to the Revised Sequence Listing submitted herewith *via* EFS-Web. The specification has been amended to include the corresponding sequence identifiers. Furthermore, the specification has also been amended to include a paragraph directed to the incorporation of the Sequence Listing submitted *via* EFS-Web. No new matter has been added to the Sequence Listing or the specification. Entry of this Sequence Listing into the application is requested.

Claim Objections

The status of claim 22 has been appropriately corrected.

The Examiner objected to claims 4, 5, 13, 16, and 21 for the recitation of a sequence motif without a sequence identifier. In light of the amendments, the objection is believed to be rendered moot. Withdrawal of the objection is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Claim 13 was rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Applicants respectfully disagree and traverse the rejection.

The Examiner alleges that a representative number of species falling within the scope of promoter sequences having the designation GOS2 is not described in the specification, nor the structural features unique to the genus that are correlated to the functional attributes of a GOS2 promoter.

GOS2 promoters are known promoters, for example, the GOS2 promoter from rice was known from de Pater *et al.* as described in the specification and as acknowledged by the Examiner. As another example, a GOS2 promoter from corn was also known, as shown in WO 00/20571. A patent need not disclose what is well known to those skilled in the art and preferably omits that which is well known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). Furthermore, it is unnecessary for a patent application to provide a description of nucleotide sequences which are already known in the prior art. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1367, 79 USPQ2d 1001, 1008 (Fed. Cir. 2006). Moreover, there has never been a requirement that every species encompassed by a claim must be disclosed or exemplified in a working example. *In re Angstadt*, 537 F.2d 498 (CCPA 1976).

As explained in *Capon v. Eshhar*, 418 F.3d 1349, 1358, 76 USPQ2d 1078, 1084-5 (Fed. Cir. 2005):

The “written description” requirement must be applied in the context of the particular invention and the state of the knowledge. The Board’s rule that the nucleotide sequences of the chimeric genes must be fully presented, although the nucleotide sequences of the component DNA are known, is an inappropriate generalization. When the prior art includes the nucleotide information, precedent

does not set a *per se* rule that the information must be determined afresh. Both parties state that a person experienced in the field of this invention would know that these known DNA segments would retain their DNA sequences when linked by known methods. Both parties explain that their invention is not in discovering which DNA segments are related to the immune response, for that is in the prior art, but in the novel combination of the DNA segments to achieve a novel result.

Similarly as explained by the Federal Circuit in *Falko-Gunter Falkner v. Inglis*, citing to *Capon*:

“Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in *Capon*, “[t]he ‘written description’ requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.” *Id.* at 1358. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification. Accordingly we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here “essential genes”), satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences.” *Falko-Gunter Falkner v. Inglis*, 448 F.3d at 1368.

The court in *Falko-Gunter Falkner* in discussing *Eli Lilly* further reiterates the holding of *Capon* as follows:

“However, it is the binding precedent of this court that *Eli Lilly* does *not* set forth a *per se* rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art. *See Capon*, 418 F.3d at 1357 (“None of the cases to which the Board attributes the requirement of total DNA re-analysis, i.e., *Regents v. Lilly*, *Fiers v. Revel*, *Amgen*, or *Enzo Biochem*, require a re-description of what was already known.”).

Similar to the holdings in *Falko-Gunter Falkner* and *Capon*, Applicants submit that the present specification does provide adequate written description because a GOS2 promoter is described in the specification and GOS2 promoters were known in the art. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claim 13 was rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Fabian-Marwedel *et al.* (hereinafter “Fabian-Marwedel”) in view of de Pater B.S. *et al.* (hereinafter “de Pater”). Applicants respectfully disagree and traverse the rejection. Nonetheless, claim 13 has been amended without prejudice or disclaimer to clarify the nucleic acid sequence of the construct.

The examiner bears the initial burden of establishing *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

Fabian-Marwedel does not teach or suggest a nucleic acid sequence which comprises the nucleic acid sequence of SEQ ID NO: 1, a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO: 2, or a nucleic acid sequence encoding a polypeptide comprising an amino acid sequence having at least 95% identity to SEQ ID NO: 2 as recited in present claim 13.

The Examiner acknowledges that Fabian-Marwedel does not teach a GOS2 promoter and relies on de Pater for this teaching. However, de Pater does not remedy the deficiency of Fabian-Marwedel. De Pater does not teach or suggest the nucleic acid as recited in claim 13. Neither Fabian-Marwedel nor de Pater, alone or in combination, teach or suggest the particular combination of sequences as recited in the construct of claim 13. Because neither Fabian-Marwedel nor de Pater, alone or in combination, teach or suggest all the claim limitations, a *prima facie* case of obviousness has not been established.

In light of the amendments, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1-9, 12, 15, 18, 20-21, and 23-24 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Fabian-Marwedel in view of Komari *et al.* (hereinafter “Komari”).

Applicants respectfully disagree and traverse the rejection for the reasons already of record and additionally for the following reasons.

The Examiner relies on Fabian-Marwedel for teaching rice plants cells transformed with a construct comprising a CDKD encoding nucleic acid, a maize ubiquitin promoter, and a nopaline synthase terminator sequence. The Examiner contends that Fabian-Marwedel further teaches that increasing the abundance R2 abundance accelerates S-phase progression and growth rate in suspension cells. The Examiner acknowledges that Fabian-Marwedel does not teach a transformation method where transgenic plants are produced. The Examiner relies on Komari for teaching transformation methods wherein transgenic cereal plants are produced. The Examiner also acknowledges that neither Fabian-Marwedel nor Komari teach a transgenic plant having increased yield or increasing plant yield relative to a corresponding wild type plant.

The Examiner now alleges that the increased yield recited in the claims is the end result of practicing the method and is thus inherent to the method. Applicants respectfully disagree with the Examiner's characterization of the references and conclusions and strongly disagree with the applicability of inherency in the context of the obviousness rejection.

It is well established that inherency of missing features/limitations is limited to the context of anticipation under 35 U.S.C. § 102. In other words, obviousness under 35 U.S.C. § 103(a) cannot be established through inherency. Furthermore, inherency may not be established by probabilities or possibilities and "[t]he mere fact that a certain thing *may* result from a given set of circumstances is not sufficient [to establish inherency]." See *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). "That which may be inherent is not necessarily known. **Obviousness cannot be predicated on what is unknown**," even if the inherency of a certain feature is later established. *Id.* (emphasis added). As found by the court in *In re Antonie*, which reversed the Board's finding of obviousness, it is the invention as a whole, and not some part of it, which must be obvious under 35 U.S.C.S. § 103. *In re Antonie*, 559 F.2d 618, 619-620 (CCPA 1977); see also MPEP § 2141.02 V. Furthermore, the court in *In re Antonie* found that the prior art did not reveal the property which appellant discovered and, therefore, there was no basis to find obviousness. *Id.*

Because the references cited by the Examiner do not teach, suggest or even mention a method which results in a transgenic plant having increased yield relative to a corresponding wild-type plant, let alone methods which comprise selecting a plant having increased seed yield relative to a corresponding wild-type plant, there is no basis for finding obviousness. Moreover, analogous to *In re Antonie*, Fabian-Marwedel did not recognize from expression of the gene in a cell suspension that increased plant yield or increased seed yield in a whole plant could result. For this additional reason, a *prima facie* case of obviousness has not been established.

Nonetheless in order to expedite prosecution, the claims have been amended without disclaimer or prejudice and relate to methods which include a step of selecting a transgenic plant having increased seed yield relative to a corresponding wild type plant. Because neither Fabian-Marwedel nor Komari teach a transgenic plant having increased seed yield or increasing seed yield relative to a corresponding wild type plant, Fabian-Marwedel and Komari, alone or in combination, do not disclose or suggest all the limitations of the claimed invention. Accordingly, a *prima facie* case of obviousness has not been established for this reason alone.

The Examiner maintained the rejection regarding hybridization because the claims allegedly did not recite specific hybridization conditions. Applicants strongly disagree. The claims clearly recited that the hybridization conditions were stringent conditions. One skilled in the art would clearly understand what stringent conditions represent. As explained in the Amendment and Reply Under 37 CFR § 1.111 dated January 21, 2009, based on the sequence alignment provided by the Examiner, only a 39.8% identity was found over 924 bases from a total of 1764 bases of the sequence of Accession No. X58194 dated April 18, 2005. The identity based on the full-length sequence of SEQ ID NO: 1 would thus be much less than 39.8% identity. It is the Examiner's burden to establish *prima facie* obviousness. The Examiner has not established that hybridization under stringent conditions could occur with a percent identity of less than 39.8% over only a portion of SEQ ID NO: 1.

Nonetheless, in order to expedite prosecution, the claims have been amended without disclaimer or prejudice and provide further hybridization conditions. In light of the above, the rejection as to hybridization is believed to be rendered moot. Reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner further maintains that neither Fabian-Marwedel nor Komari need teach that an effect observed in suspension cells could be reproduced in whole plants, since one skilled in the art would allegedly be apprised that whole plants comprise cells including dividing cell as characteristic of cells in suspension. The Examiner concludes that the increased yield would be inherent in the method. Applicants strongly disagree with the Examiner's interpretation and conclusions.

As mentioned above, inherency is inapplicable in the present context since obviousness cannot be predicated on what is unknown. A transgenic plant having increased yield or increasing plant yield relative to a corresponding wild type plant or a transgenic plant having increased seed yield or increasing seed yield relative to a corresponding wild type plant was unknown from the teaching of Fabian-Marwedel and Komari as even acknowledged by the Examiner.

Furthermore, inherency, which is the basis for the Examiner's obviousness rejection, may not be established by probabilities or possibilities and "[t]he mere fact that a certain thing *may* result from a given set of circumstances is not sufficient [to establish inherency]." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). The characteristic of increased growth rate of cells in suspension does not necessarily translate to how cells would grow or interact within a particular tissue, or once differentiated into a particular type of cell, tissue or organ, let alone into a plant as a whole. There is no indication in Fabian-Marwedel in view of Komari whether this growth rate would translate into an increase in plant yield let alone an increase in seed yield. To the contrary, strong overexpression in transgenic cells was found to likely have a deleterious effect (Fabian-Marwedel, page 201, left column, second full paragraph). The Examiner's assertion that because whole plants are made up of cells, these cells would have the characteristics of the cells in suspension is mere conjecture which is an improper basis for inherency assuming *arguendo* inherency was applicable.

Moreover, assuming *arguendo* inherency was applicable, it is the extrinsic evidence that "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *In re*

Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Additionally, it is the record that must provide evidence that those of skill in the art would have had a reasonable expectation of success. *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Nothing in the record provides any evidence that the methods described in Fabian-Marwedel in view of Komari provide transgenic plants having increased yield or increased seed yield relative to a corresponding wild-type plant as required or that there would be an expectation of success. Accordingly, a *prima facie* case of obviousness has not been established for these additional reasons.

Claims 16-17 and 24 remain rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Fabian-Marwedel in view of Komari and Cornejo M. *et al.* (hereinafter "Cornejo"). Applicants respectfully disagree and traverse the rejection for the reasons already of record and additionally for the following reasons. However, in order to expedite prosecution, the claims have been amended without prejudice or disclaimer and relate to transgenic plants having increased seed yield.

The explanations provided above for Fabian-Marwedel and Komari are equally applicable to this rejection and are incorporated herein in their entirety.

The Examiner states that the rejection is based on the reasons already of record in the office action mailed August 19, 2008. In that Office Action, the Examiner contends that it would be obvious to produce a transgenic plant transformed with a construct comprising a rice plant CDK-activating kinase R2 encoding nucleic acid and a maize ubiquitin promoter given that Fabian-Marwedel allegedly teaches that rice plant cells transformed with a construct comprising a rice plant CDK-activating kinase R2 encoding nucleic acid and a maize ubiquitin promoter have an accelerated S-phase progression and overall growth rate, that the control of R2 kinase activity is linked to cell proliferation in planta, as the CTD kinase activity of R2 is increased in cells induced to divide rapidly, and that R2 overexpression increases growth of rice cells in suspension resulting in increased fresh weight in transgenic cells, and given the teaching of Komari that production of transgenic rice plants was known.

The examiner bears the initial burden of establishing *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

In Fabian-Marwedel, overexpression of R2 was analyzed at the transcript level and at the protein level in transgenic cells in suspension. Fabian-Marwedel however discloses that they could not isolate transgenic cell lines with higher R2 protein levels, likely because of deleterious effects of a strong overexpression on the cells. (Fabian-Marwedel, page 201, left column, second full paragraph). In transgenic cells in suspension, R2 overexpression affected cell cycle progression with premature entry into and accelerated passage through S-phase. (Fabian-Marwedel, page 205, left column, third paragraph). However, the possible increased growth of the cell population could not be attributed to whether R2 overexpression affected cell size or cell division rate. (Fabian-Marwedel, page 202, left column, first paragraph; page 205, left column, third paragraph).

The expression of R2 was also analyzed in non-transgenic rice plants either during normal growth or after induction of rapid growth by partial submergence. (Fabian-Marwedel, page 202, left column, second paragraph). Fabian-Marwedel concluded that R2 played a role in S-phase entry and/or progression through DNA replication based on CTD kinase activity being highest in the meristem after induction in non-transgenic plants. However, no induction of CTD kinase activity of R2 was measured in the elongation zone or the differentiation zone, and, in non-induced plants, transcript levels of R2 were comparable in the meristem and differentiation zone but higher in the elongation zone. (Fabian-Marwedel, page 202, left column last paragraph and right column, last two paragraphs). Moreover, R2 levels varied at the transcript, protein, and CTD kinase activity level during the mitotic cell cycle in non-transgenic plants. (Fabian-Marwedel, page 205, left column, first paragraph). Fabian-Marwedel also concluded that it was not resolved whether the CTD or CAK kinase activity of R2 or both was responsible for the observed acceleration of S-phase. (Fabian-Marwedel, page 205, left column, last paragraph). This suggested effect on acceleration through the S-phase in a non-transgenic plant would not provide any indication on the effect on yield or seed yield of a transgenic plant since even in an

induced non-transgenic plant no affect was observed in the elongation zone or the differentiation zone. The record must provide evidence that those of skill in the art would have had a reasonable expectation of success. *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

The suggested characteristic of an R2 effect on S-phase progression and increased growth of transgenic cells in suspension does not indicate how transgenic cells would grow or interact within a particular tissue, or once differentiated into a particular type of cell, tissue or organ, let alone into a transgenic plant as a whole. Further there is no indication whether growth of suspension cells or effects on S-phase progression would translate into an increase in seed yield or have any affect on yield or seed yield of a transgenic plant. To the contrary, strong overexpression in transgenic cells was found to likely have a deleterious effect. Nothing in Fabian-Marwedel teaches or suggests a transgenic plant having increased yield or increased seed yield relative to a corresponding wild type plant as even acknowledged by the Examiner.

The teaching in Cornejo of a maize ubiquitin promoter or in Komari of a method of transforming rice plants does not remedy the deficiencies of Fabian-Marwedel. None of the references cited by the Examiner, alone or in combination, teach or suggest a transgenic plant with increased yield or seed yield relative to a corresponding wild-type plant as required or that there would be an expectation of success of obtaining such plants as explained above. Because Fabian-Marwedel, Komari, and Cornejo, alone or in combination, do not teach or suggest all the claim limitations, a *prima facie* case of obviousness has not been established for this reason alone.

Moreover, as explained above, obviousness cannot be predicated on what is unknown. A transgenic plant having increased seed yield relative to a corresponding wild type plant as claimed was unknown from the teaching of Fabian-Marwedel, Komari, and Cornejo. Accordingly, Fabian-Marwedel, Komari, and Cornejo do not render the claims obvious.

For at least these reasons, reconsideration and withdrawal of the rejection is respectfully requested for the independent claims and the claims dependent therefrom. *See In re Fine*, 837

F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Accompanying this response is a Request for Continued Examination (RCE) and a petition for a two-month extension of time to and including September 15, 2009 with the required fee authorization. No further fee is believed due. If any additional fee is due, please charge our Deposit Account No. 03-2775, under Order No. 14546-00001-US from which the undersigned is authorized to draw.

Respectfully submitted,

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